K120127

SWAN VALLEY MEDICAL
INCORPORATED

OCT 26 2012

510(k) SUMMARY

Swan Valley Medical
Transurethral Suprapubic endo-Cystostomy
(T-SPeC™) Surgical System

I. Submitter Information

510(k) Owner:	Swan Valley Medical, Incorporated Harbor Village 301 Eagle Bend Drive P.O. Box 3005 Bigfork, MT 59911 USA
Sponsor Contact:	Mr. Ronald E. Zook, President and CEO 406-837-1500 (office) 406-837-1532 (fax)
Submission Correspondent / Consultant:	Kevin Randall, Principal Consultant ComplianceAcuity, Inc. 16576 W. 53rd Way Golden, CO 80403 (303) 828-0844 (direct) (303) 828-0835 (fax) Email: info@complianceacuity.com
Date Summary Prepared:	January 16, 2012

II. Name of Device

Trade Name:	Swan Valley Medical Transurethral Suprapubic endo-Cystostomy (T-SPeC™) Surgical System
Common/Usual Name:	Suprapubic Catheter and Accessories
Classification Name:	Suprapubic urological catheter and accessories (21 CFR 876.5090, Product Code KOB)

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III. Device Description

The T-SPeC™ Surgical System is, in effect, a sterile suprapubic catheter and accessory kit consisting of a) a suprapubic catheter; b) a catheter punch instrument used to create a cystostomy and place the suprapubic catheter; and c) a piston syringe to fill the catheter balloon after placement. As provided and configured in this kit, none of these constituents are legally marketed devices. Therefore each constituent is itemized in this section 510(k) notification.

IV. Intended Use

The Swan Valley Medical Transurethral Suprapubic endo-Cystostomy (T-SPeC™) Surgical System is intended for suprapubic bladder catheterization (cystostomy) and drainage.

V. Identification of / Comparison to Legally Marketed Predicates

The predicate devices to which substantial equivalence is being claimed are tabulated below:

Predicate Device	Manufacturer	510(k)	Relevance
Fortune Suprapubic Catheter	Fortune Medical Instrument Corp.	K014002	T-SPeC™ Suprapubic Catheter intended for bladder drainage.

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Predicate Device	Manufacturer	510(k)	Relevance
Lowsley Suprapubic Tractor	Circon Corp. (now owned by Gyrus ACMI, Inc.)	K012153	T-SPeC™ Catheter Punch Instrument: • "inside-out" cystostomy via transurethral bladder access • Capture and placement of Suprapubic Catheter
Qlicksmart BladeFLASK and BladeSINGLE	Qlicksmart Pty., Ltd.	K983367	Sharps containment feature of the T-SPeC™ Catheter Punch Instrument.
Omnifix® Syringe	B. Braun Medical Inc.	K071459	T-SPeC™ Piston Syringe for inflating/deflating catheter balloon

Each component of the T-SPeC™ Surgical System was compared to the corresponding predicate based on various design and performance factors.

VII. Summary of Non-Clinical Performance Data

To support the substantial equivalence claim made herein, various bench performance studies have been performed related to:

• Suprapubic Catheter design and performance.	• Biocompatibility
• Catheter accessory design and performance.	• Sterilization Validation & Shelf Life

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VIII. Summary of Clinical Performance Data

No clinical performance testing was performed. Substantial equivalence for the subject device is based on the aforementioned non-clinical bench studies.

IX. Conclusions Drawn

As demonstrated by the predicate device comparisons herein, The Swan Valley Medical Transurethral Suprapubic endo-Cystostomy (T-SPeC™) Surgical System has the same intended use as the legally marketed predicates but incorporates different technological characteristics. Nevertheless, the performance data submitted in support of this section 510(k) Notification demonstrate that the modified technological characteristics do not adversely affect the safety and effectiveness of the subject device. Based on these facts, it is therefore the conclusion of Swan Valley Medical Incorporated that the subject device is as safe and as effective, that is, "substantially equivalent" to, the predicates pursuant to section 513(i) of the Act.

END OF 510(k) SUMMARY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

OCT 2 6 2012

Swan Valley Medical, Incorporated
% Mr. Kevin Randall
Principal Consultant
ComplianceAcuity, Inc.
16576 W. 53rd Way
GOLDEN CO 80403

Re: K120127
Trade/Device Name: Swan Valley Medical Transurethral Suprapubic endo-Cystostomy (T-SPeC®) Surgical System
Regulation Number: 21 CFR§ 876.5090
Regulation Name: Suprapubic urological catheter and accessories
Regulatory Class: II
Product Code: KOB, FEX
Dated: October 11, 2012
Received: October 12, 2012

Dear Mr. Randall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120127

Device Name:

Swan Valley Medical Transurethral Suprapubic endo-Cystostomy (T-SPeC®) Surgical System

Indications For Use:

The Swan Valley Medical Transurethral Suprapubic endo-Cystostomy (T-SPeC®) Surgical System is intended for suprapubic bladder catheterization (cystostomy) and drainage. The catheter should not be allowed to remain indwelling for more than 29 days.

Prescription Use X **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(Part 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120127